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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,752	09/10/2003	Corinna Lohning	49974-006	4532
61263 7590 04/06/2009 PROSKAUER ROSE LLP 1001 PENNSYLVANIA AVE, N.W., SUITE 400 SOUTH WASHINGTON, DC 20004				
EXAMINER				
STEELE, AMBER D				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/658,752

Applicant(s)

LOHNING, CORINNA

Examiner

AMBER D. STEELE

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 71-112 is/are pending in the application.
- 4a) Of the above claim(s) 76-78, 80-84, and 89-112 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 71-75, 79 and 85-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/809,517.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-649)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 17, 2008 has been entered.

Status of the Claims

2. Claims 1-31 were originally filed on September 10, 2003.

The claim amendment received on December 10, 2003 canceled claims 1-16 and 24-31 and amended claims 18-19 and 22-23.

The claim amendment received on November 28, 2005 amended claim 18.

The claim amendment received on July 25, 2006 canceled claims 17-23 and added new claims 32-67. However, the claim amendment was not entered (see the Notice of Non-Compliant Amendment mailed August 1, 2006).

The claim amendment received on September 1, 2006 canceled claims 17-23 and added new claims 32-67. However, the claim amendment was not entered (see the Notice of Non-Compliant Amendment mailed on February 1, 2007).

The claim amendment received on March 1, 2007 amended claims 18 and 21-22, canceled claims 17, 19-20, and 23, and added new claims 32-34.

The amendment to the claims received on September 17, 2008 canceled claims 18, 21-22, and 32-34 and added new claims 35-70.

The amendment to the claims received on February 2, 2009 canceled claims 35-70 and added new claims 71-112.

Claims 71-112 are currently pending.

Claims 71-75, 79, and 85-88 are currently under consideration.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 75, 78, 80-82, and 97-104, drawn to an isolated host cell comprising two vectors wherein one vector comprises a variant of a WT bacteriophage coat protein wherein the variant comprises additions and the other vector comprises a coding sequence for a polypeptide, classified in class 435, subclass 320.1.
 - II. Claims 76, 78, 80-81, 83, 89-92, 97-100, and 105-108, drawn to an isolated host cell comprising two vectors wherein one vector comprises a truncated WT bacteriophage coat protein, classified in class 435, subclass 252.1.
 - III. Claims 77-78, 80-81, 84, 93-100, and 109-112, drawn to an isolated host cell comprising two vectors wherein one vector comprises a truncated WT bacteriophage coat protein with additions, classified in class 435, subclass 252.1.
 - IV. Claims 75 and 79, drawn to an isolated host cell comprising a vector comprising a variant of a WT bacteriophage coat protein wherein the variant comprises additions and another coding sequence for a polypeptide, classified in class 536, subclass 23.53.

- V. Claims 76, 79, and 89-92, drawn to an isolated host cell comprising a vector comprising a truncated WT bacteriophage coat protein and another coding sequence for a polypeptide, classified in class 435, subclass 320.1.
- VI. Claims 77, 79, and 93-96, drawn to an isolated host cell comprising a vector comprising a truncated WT bacteriophage coat protein with additions and another coding sequence for a polypeptide, classified in class 536, subclass 23.53.

Linking Claims

4. Claim 71-74 and 85-88 link(s) inventions I-VI. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 71-74 and 85-88. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the

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provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

5. The inventions are distinct, each from the other because of the following reasons:

A. Inventions I-VI are directed to related products. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design, mode of operation, function, or effect. For example, Groups I and IV require a variant of a WT bacteriophage coat protein comprising additions, while Groups II and V require a truncated WT bacteriophage coat protein, and Groups III and VI require a truncated WT bacteriophage coat protein with addition. In addition, Groups I-III require two vectors and Groups IV-VI require a single vector. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

6. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;

- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

7. Applicant's election with traverse of Group IV (now claims 71-75, 79, and 85-88) in the reply filed on February 2, 2009 is acknowledged. The traversal is on the ground(s) that a serious search burden does not exist. This is not found persuasive because a search burden does exist due to the different structures (e.g. two vectors, single vector, additions, truncations, etc.).

The requirement is still deemed proper and is therefore made FINAL.

Priority

8. The present application claims status as a DIV of 09/809,517 filed March 15, 2001 (now U.S. Patent 6,753,136) which is a CON of PCT/EP00/06968 filed July 20, 2000. The present application claims foreign priority to EP 99 11 4072.4 filed July 20, 1999 and EP 00 10 3551.8 filed February 18, 2000.

9. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or

provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application No. EP 99 11 4072.4 and EP 00 10 3551.8 (foreign priority), fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The foreign priority documents do not provide support for the limitations of claim 75 (i.e. between one and six additional amino acid residues). Claim 75 has a priority date of July 20, 2000.

Invention as Claimed

10. An isolated host cell comprising: (i) a nucleic acid sequence encoding a variant of a wild type coat protein of a bacteriophage wherein said variant comprises at least one part of said wild type coat protein of a bacteriophage wherein said at least one part comprises at least that part which causes or allows the incorporation of said coat protein into the phage coat and wherein said variant does not contain an interaction domain for interaction with a second domain present in the (poly)peptide/protein and (ii) one or more nucleic acid sequences encoding a (poly)peptide/protein comprising a cysteine residue wherein upon expression of said nucleic acid sequence encoding a coat protein and said one or more nucleic acid sequences encoding a (poly)peptide/protein comprising a cysteine residue attachment of said coat protein and said (poly)peptide/protein occurs by formation of a disulfide bond between said cysteine residue in said coat protein and said cysteine residue comprised in said (poly)peptide/protein and variations thereof.

11. The present invention is drawn to a host cell which comprises nucleic acid sequences. While functional language which requires a certain structure will be provided patentable weight (e.g. nucleic acid encodes variant of a wild type coat protein of a bacteriophage), limitations regarding the polypeptides after expression will not be provided patentable weight except for the implied structure (e.g. nucleic acid encodes cysteine). See MPEP § 2173.05(g).

Withdrawn Objection

12. The objection to claim 22 is moot due to the cancellation of the claim.

Maintained Objection

Drawings

13. The drawings/figures are objected to because tables and sequence listings included in the specification must not be duplicated in the drawings. See 37 CFR §1.58(a) and §1.83(a). Applicants are advised that upon issuance of a patent, the complete text of the sequence listing submitted in compliance with 37 CFR §§1.821-1.825 will be published as part of the patent. Applicants should amend the specification to delete any figures/drawings which consist only of nucleic acid or protein sequences which have been submitted in their entirety in computer readable format and should further amend the specification accordingly to reflect the replacement of the drawing/figure by the appropriate SEQ ID NO:. Applicants may also amend the drawings containing sequences to point out various structures, etc. which would provide additional information not found in the sequence listing.

Appropriate correction is required.

Arguments and Response

14. Applicants' arguments directed to the objection to the drawings regarding the duplication of sequences in the drawings were considered but are not persuasive for the following reasons.

Applicants contend that 37 CFR § 1.58(a) and § 1.83(a) were amended in 2004 long after the instant application was filed therefore the instant application was fully in compliance with the requirements in force at the time of filing of the instant application.

Applicants' arguments are not convincing since the drawings duplicate sequences in the sequence listing without providing additional information. It is noted that the present application was not examined on the merits until January 25, 2006 at which time 37 CFR § 1.58(a) and § 1.83(a) were amended.

Withdrawn Rejections

15. The rejection of claim 33 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is moot in view of the cancellation of the claim.

16. The rejection of claims 18, 21-22, and 32-34 under 35 U.S.C. 103(a) as being unpatentable over Dower et al. U.S. Patent 5,427,908 issued June 27, 1995 and Kipriyanov et al. 1994 Molecular Immunology Volume 31 Number 4 pages 1047-1058 "Recombinant single-chain Fv fragments carrying C-terminal cysteine residues: production of bivalent and biotinylated miniantibodies" is moot in view of the cancellation of the claims.

17. The provisional rejection of claims 18, 21-22, and 32-34 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 32-41 of copending Application No. 11/680,259 is moot in view of the cancellation of the claims.

New Rejections Necessitated by Amendment

Claim Rejections – 35 USC § 112

18. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

19. Claims 71-75, 79, and 85-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **new matter** rejection. Applicants have not pointed out support for new claims 71-75, 79, and 85-88 in the originally filed specification. Applicant should specifically point out the support for any amendments made to the disclosure. See MPEP § 2163.06.

20. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

21. Claims 71-75, 79, and 85-88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 71 recites the limitation "said nucleic acid encoding a coat protein" in line 10. There is insufficient antecedent basis for this limitation in the claim.

B. Claim 71 recites the limitation "the (poly)peptide/protein" in line 6. There is insufficient antecedent basis for this limitation in the claim.

C. Claim 71 recites the limitation "said cysteine residue in said coat protein" in the next to last line. There is insufficient antecedent basis for this limitation in the claim.

D. Claim 71 recites the limitation "said coat protein" in lines 12 and 13. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

22. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

23. Claims 71-72, 74-75, 79, and 85-88 are rejected under 35 U.S.C. 102(b) as being anticipated by Dower et al. U.S. Patent 5,427,908 issued June 27, 1995.

For present claims 71-72, 75, and 79, Dower et al. teach host cells comprising a vector comprising nucleic acids encoding a bacteriophage coat protein which has been fused to additional amino acids (i.e. modified variant of a wild type coat protein comprising a cysteine residue) and comprising a nucleic acids encoding a polypeptide comprising a cysteine residue (i.e. VL or VH; please refer to the entire specification particularly the abstract; column 2, lines 44-61; column 4, lines 65-67; column 5, lines 1-13; column 6, lines 1-14; columns 7-9 and 14-15).

For present claim 74, Dower et al. teach nucleic acid also encodes one or more peptide sequences for purification including tag proteins which are about 3 to about 100 amino acids in length (please refer to the entire specification particularly column 1, lines 60-67; column 2, lines 1-13; column 5, lines 38-67; column 6, lines 1-14; column 7, lines 19-65).

For present claim 85, Dower et al. teach bacterial host cells (please refer to the entire specification particularly column 1, lines 60-67; column 6, lines 21-27; columns 9-10).

For present claim 86, Dower et al. teach filamentous bacteriophage (please refer to the entire specification particularly column 2, lines 14-61; column 7, lines 54-65; column 8, lines 31-57; columns 9-10).

For present claims 87-88, Dower et al. teach antibodies, Fab, Fv, VH, and VL (please refer to the entire specification particularly column 3, lines 18-42; column 4, lines 65-67; column 5, lines 1-13).

Therefore, the presently claimed host cell is anticipated by the teachings of Dower et al.

Double Patenting

24. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

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with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

25. Claims 71-75, 79, and 85-88 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42-67 of copending Application No. 11/680,259. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed invention and the invention as claimed in U.S. application 11/680,259 are drawn to host cells comprising a vector for phage display via cysteine residues.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMBER D. STEELE whose telephone number is (571)272-5538. The examiner can normally be reached Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Amber D. Steele/
Primary Examiner, Art Unit 1639

March 31, 2009